Defense Threat Reduction Agency
8725 John J. Kingman Drive, MS 6201
Ft. Belvoir. VA 22060-6201

JUSTIFICATION FOR OTHER THAN FULL AND OPEN COMPETITION

1. Description of action

The Defense Threat Reduction Agency (DTRA), performing contracting activity for the U.S. Air Force Assistant Surgeon General, Modernization Directorate (AF/SGR), proposes to procure without using full and open competition a Firm Fixed Price contract requirement with Idaho Technology, Inc. (ITI), 390 Wakara Way, Salt Lake City, Utah 84108 to provide for the AF/SGR Epidemic Outbreak Surveillance (EOS), Advanced Concept Technology Demonstration (ACTD) further development of an advanced diagnostic system (FilmArray™) for pathogen detection requirements in conjunction with the U.S. Army Medical Research Institute of Infectious Diseases (USAMRIID).

The contract shall include a 24 month period of performance from date of award. The total dollar value for this action is estimated at $3,387,236.66.

The AF/SGR EOS program serves as the Program Manager and Contracting Officer's Representative for two efforts supporting advanced diagnostic device development. The ITI FilmArray™ system is currently under contract with the AF/SGR (Contract no. FA7014-08-C-0004) for FDA clinical trials, packaging ruggedization, software connectivity and CLIA Waiver Plan development through FY10 that supports the EOS ACTD and joint services mission to provide a real-time diagnostic clinical Point of Care (POC) device. Under a Congressionally funded directed appropriation (under the provisions of the Competition in Contracting Act of 1984 (Public Law 98-369), as implemented in the Federal Acquisition Regulation (FAR)), the AF/SGR is also managing the delivery of multiple FilmArray™ devices to AF sites for mission orientation evaluation, military utility assessment and CONOPS development under AF BAA09-01 to be placed under contract in FY10 with work effort through FY11.

2. Description of the supplies/services required

This requirement is for the purpose of providing continued development of the highly specialized ITI FilmArray™ system. This system integrates sample preparation, Polymerase Chain Reaction (PCR) amplification, detection and analysis into one easy-to-use system capable of detecting greater than 100 targets in one sample in less than one

hour. The FilmArray™ pouch is a closed system containing all the required reagents in a freeze-dried formulation. The EOS Program, funded by AF/SGR, currently has a contract with ITI (FA7014-08-C-0004) for clinical trials on a Respiratory Panel (RP) that identifies 20 common and emerging bacterial and viral respiratory pathogens; modifying and testing a ruggedized packaging for the device; enabling a software link between the device and military databases; and developing a plan for Clinical Laboratory Improvement Amendments (CLIA) waiver (reference: Department of Health and Human Services, 42 CFR Part 493 Medicare, Medicaid, and Clinical Laboratory Improvement Amendments of 1988 CLIA Program).

Under the current contract, IIT will develop a CLIA plan. During analytic and clinical evaluations, the accuracy of test results and the adequacy of existing control measures will be evaluated. When failure modes are encountered, appropriate measures are being taken to eliminate or reduce the incidence of erroneous results to an insignificant level. This information will be used to prepare a plan to obtain CLIA waived status for the FilmArray™. The plan includes testing in the intended user setting, possibly forward military laboratories, and exposing the system to a variety of environmental stress and human errors.

The contract proposed under this J&A is to continue the development of the FilmArray™, implementing the CLIA plan and all required work efforts for submission of the CLIA Waiver Application for Food and Drug Administration (FDA) approval. The following tasks will be included:

1. Provide Project Management of the CLIA Waiver Effort
2. Conduct Risk Analysis
3. Develop and Execute Flex Studies
4. Pre-clinical FilmArray™ System Placements
5. Go-Forward Plan Submission
6. Implement System Modifications
7. Conduct Specific CLIA Waiver Clinical studies
8. Submit a CLIA Waiver Application

In addition, the follow-on work covered by this J&A will expand the identification capability to include additional infectious organisms to accelerate the development specifically of infectious pathogens that are not on the official BioThreat (BT) list for thorough performance assessment tests. Having an FDA CLIA waived device ready for training and deployment would enhance the utility of the platform in a deployed setting, ultimately protecting the warfighter.

ITI FilmArray™ RP pouches are ready for clinical trials now. The BT pouches are developed at laboratory-scale but have not had a thorough performance assessment.

Currently identified as a moderately complex device, completing the work for CLIA waiver would allow the device to be used with minimal training (to non-laboratory personnel) in any setting. According to FDA requirements, FDA approval is a pre-requisite for obtaining CLIA waiver. In addition, obtaining a CLIA waived status requires that the device as defined by CLIA 88 "must be simple laboratory examinations and procedures that have an insignificant risk of an erroneous result." The current AF/SGR contract with ITI includes deliverables for obtaining FDA approval, and ITI believes that the FilmArray™ can meet FDA's CLIA test requirements.

Infectious and emerging disease continues to be a formidable opponent for both garrison and deployed troops. There is currently no technology for pathogen identification that can easily identify numerous pathogens simultaneously (to include BT pathogens), has integrated sample preparation, occurs in less than three hours, or is CLIA waived for ease of use by novice laboratories.

3. Statutory Authority:

The statutory authority for this non-competitive action is:

10 U.S.C. 2304(c)(1), as implemented by Federal Acquisition Regulation 6.302-1, Only One Responsible Source.

4. Applicability of Authority

This requirement is a logical follow-on procurement to the AF/SGR contract with ITI, the manufacturer of the proprietary FilmArray™ system. The Deputy Assistant Secretary of Defense for Force Health Protection and Readiness has determined that additional deployable medical devices should be identified for acceleration toward fielding. ITI is the patent holder of the FilmArray™ and no other single device can test for numerous pathogens concurrently within a closed system.

The ITI FilmArray™ currently leads the technology base in meeting these DoD requirements, as objectively evaluated by Johns Hopkins Applied Physics Laboratory in March 2009. Availability of a CLIA-waived field test for common and emerging respiratory pathogens, as well as BT pathogens, with sample to result in one hour, provides DoD a near real-time force protection capability. This capability will result in the right treatment for the individual warfighter, as well as, allowing prevention and control measures to be put in place for joint force health protection purposes.

There is no CLIA-waived device of this caliber that is fielded for military use. The FilmArray™ is a dual-use device and the Army/USAMRID has a Cooperative Research and Development Agreement to do extensive performance testing with the device. In

addition, USAMRIID has also identified the FilmArray™ as a potential next generation rapid diagnostic platform. The Air Force would like to use the same device for commonality purposes for the soldier. In addition, DTRA has interest in the device for BT detection.

ITI is the only known, currently acceptable, source to meet the device needs. There are no other companies that have the advanced technology to perform the needs of the AF/SGR.

5. Effort to Solicit Potential Sources

On July 1, 2009, DTRA posted a Notice of Intent to FEDBIZOPP.GOV, which also solicited interested parties to submit their qualifications to perform the effort based on the stated requirement (Solicitation No. CBO09001595). No responses were received.

On March 16, 2009, Johns Hopkins University Applied Physics Laboratory completed a quantitative assessment (EOS ACTD Technology funded Study) on existing devices, the current state of biodetection technologies/instrument systems and the technologies that most closely align with EOS ACTD objectives. A total of 164 instrument systems were scored as part of this technology survey and more than 200 instruments, from over 100 companies, were researched. These were across the breadth of global systems from near commercial off the shelf (COTS) to COTS-based systems. The results of this study concluded that ITI Film Array is the only technology to meet DoD and EOS ACTD needs at this time.

6. Fair and Reasonable Costs

The Contracting Officer will use field pricing support from the cognizant DCAA office, input/evaluation from the project office, projections from actual and historical data taken from current files, and comparative analyses. Cost analysis as well as price analysis will be performed, and the certified cost and pricing data will be obtained from ITI.

7. Market Research

On March 16, 2009, Johns Hopkins University Applied Physics Laboratory completed a quantitative assessment (EOS ACTD Technology funded Study) on existing devices and the current state of biodetection technologies/instrument systems and the technologies that most closely align with EOS ACTD objectives. A total of 164 instrument systems were scored as part of this technology survey and more than 200 instruments, from over 100 companies, were researched. These were across the breadth of global systems from near COTS to COTS-based systems. The results of this study concluded that ITI FilmArray™ is the only technology to meet DoD and EOS ACTD needs at this time.

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Other market research used to identify potential sources included historical acquisition information (review of recent market research results for similar or identical supplies/services); a review of Government and/or commercial databases for relevant information; a review of Internet resources; the use of source lists for identical or similar items obtained from the Government, professional, and /or industry sources; a review of catalogs and other generally available product literature; contracts with the requester and/or other knowledgeable people in Government and industry regarding the commercial nature of their requirement and standard industry practices in this area of supply/service; and personal knowledge in procuring supplies/services of this type.

Based on the John Hopkins quantitative assessment, Notice of Intent posted by DTRA, no other companies were found to have the advanced technology to perform the needs of the AF/SGR.

8. Other Facts

ITI's FilmArray™ is a dual-use device and the Army USAMRID has a Cooperative Research and Development Agreement with ITI to do extensive performance testing with the device. DoD prefers compatibility for soldiers, and thus, the Air Force desires to use the same FilmArray™ device that USAMRIID has identified as a potential next generation rapid diagnostic platform. Awarding to any other source would result in a substantial duplication of cost to the Government that is not expected to be recovered through competition.

9. Interested Sources

The FEDBIZOPPS notice did not result in any interested sources. The Johns Hopkins Applied Physics Laboratory market survey and assessment on existing devices and the current state of biodetection technologies/instrument systems and the technologies that most closely align with the EOS ACTD objectives, indicate the ITI's FilmArray™ device is the leading technology that fits DoD's requirements.

10. Subsequent actions

The program manager will continuously survey the biotechnology field for possible sources of advanced sample preparation, PCR amplification and detection devices for future

consideration. Any company found to meet the requirements would be encouraged to submit a request to the Contracting Officer to offer a competing proposal. The proposal, if submitted, would be evaluated by the technical team for potential performance ability.

Technical Certification

I certify that the data and information forming the basis for this justification are accurate and complete to the best of my knowledge and belief.

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Teresa M. Herston
Contracting Officer

7 Aug 09
Date